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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,347	10/22/2002	Jerzy A. Georgiades	AAT-12792	3120
7609	7590	07/14/2005	EXAMINER	
RANKIN, HILL, PORTER & CLARK, LLP 925 EUCLID AVENUE, SUITE 700 CLEVELAND, OH 44115-1405			CHISM, BILLY D	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/980,347	GEORGIADES, JERZY A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	B. Dell Chism	1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 21-27 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 21-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Applicant's election with traverse of the species "identified by SEQ ID 1" in the reply filed on 02 May 2005 is acknowledged. The traversal is on the ground(s) that it is unlawful for the examiner to restrict within a claim that gives a Markush group of which the members have a common utility and the members are of a recognized class of chemical compounds. This is not found persuasive because the MPEP §803.02 states that:

"If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions."

If those requirements are met then the MPEP requires the examiner to follow *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978). However, the examiner is permitted to refuse to search the Markush group if there is a lack of unity wherein the members of the Markush group do not satisfy the two-pronged requirement that the members must share a common utility **and** a common structure. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Presently, the multiple amino acid sequences do not share a common structure. The lack of common structure between the many Markush members adds serious burdens to the prosecution of the application by the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-8 and 21-27 are pending. Claim 8 is withdrawn from consideration for being drawn to non-elected subject matter. Claims 1-7 and 21-27 are under consideration. Claims 1-3 and 5-7 are drawn to non-elected subject matter, however, since the claims do possess the elected

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subject matter, the claims should be amended to exclude the non-elected subject matter (i.e., all sequences that are not the elected subject matter of SEQ ID NO: 1.

### ***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-3, 4-7, 21 and 22-27 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-13 and 16-18 of U.S. Patent No. 6,903,068 B1 ('068). Although the conflicting claims are not identical, they are not patentably distinct from each other because '068 teaches in claim 11 the instantly claimed peptide of SEQ ID NO: 1 for which the instant invention is based. Additionally, '068 teaches in claim 11 the use of the peptide for modulating immune responses in a patient and is taught as a immunological regulator administered as a dietary supplement in the claim 12 of '068, is taught as a topical in claim 13 of '068, and is taught for getting specific and general immunological responses in the claims 16-18 of '068. Thus, the peptide of claims 1-7 is taught by '068 and the method of using the peptide in the method of the instant claim 21 is anticipated by '068. It should be noted that claims 4-7 are product-by-process claims wherein the product is the instantly claimed invention and therefore is anticipated by '068.

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Claims 22-27 are obvious over '068 as further supported by the specification of '068.

Claims 11-13 and 16-18 teach the uses for the instantly claimed peptide of SEQ ID NO: 1 as an in vivo regulator for immunological activities, however, the claims of '068 do not state a carrier or the possible formulations for the peptide. However, the products of claims 22-27 are obvious in light of the specification of '068 wherein the specification teaches at column 9 lines 20-43 pharmaceutical carriers, preferred injections, and preferred orally administered formulations such as syrup, gel, liquid, pill, and capsules. Therefore, claims 22-27 are obvious.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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B. Dell Chism

PATENT EXAMINER

A handwritten signature in black ink, appearing to read "B. Dell Chism", enclosed within a large, irregular oval loop.